

Teclistamab +/- Lenalidomide Versus Lenalidomide Alone as Maintenance Therapy Post-Transplant in Newly Diagnosed Multiple Myeloma: Updated Safety Run-In Results From EMN30/MajesTEC-4*

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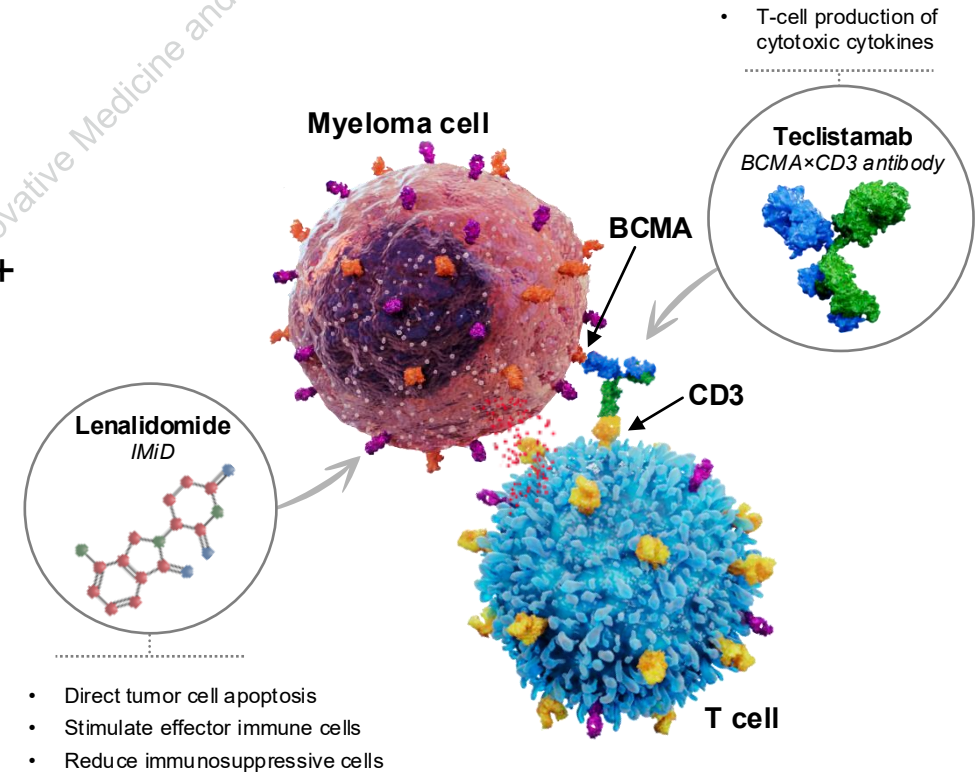
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EMN30/MajesTEC-4: Introduction

- Len is a SoC maintenance therapy in NDMM following ASCT; however, patients still relapse, highlighting the need for novel maintenance strategies¹
- Tec-based regimens are a new fully immune-based SoC in 2L+ MM, with significant PFS and OS benefits²⁻⁴
- EMN30/MajesTEC-4 is a phase 3 study evaluating Tec-Len, Tec, and Len maintenance therapy post-ASCT in NDMM⁵
 - Initial SRI results (~1-2 years of median follow-up) showed promising early safety and exceptional response rates⁶
 - **We report updated SRI safety and efficacy results with up to 3 years of median follow-up**



2L+, second-line or later; ASCT, autologous stem cell transplantation; BCMA, B-cell maturation antigen; EMN, European Myeloma Network; IMiD, immunomodulatory drug; Len, lenalidomide; MM, multiple myeloma; NDMM, newly diagnosed multiple myeloma; SoC, standard-of-care; SRI, safety run-in; Tec, teclistamab.

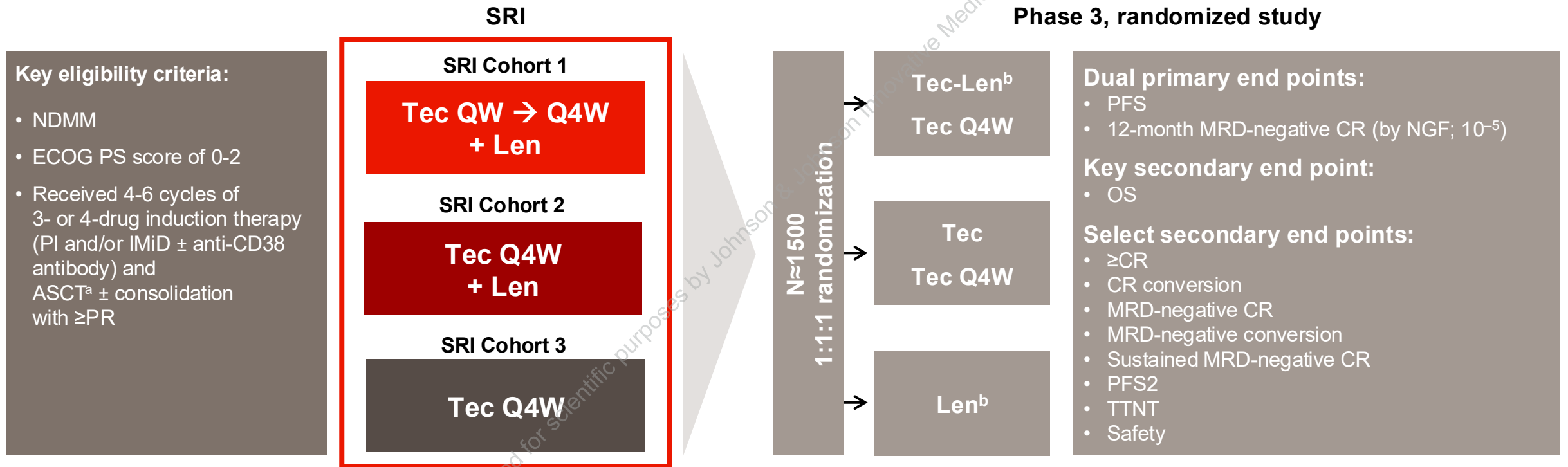
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EMN30/MajesTEC-4: Study Design



CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; MRD, minimal residual disease; NGF, next-generation flow cytometry; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival after next line of therapy; PI, proteasome inhibitor; PR, partial response; QW, weekly; Q4W, every 4 weeks; TTNT, time to next treatment.

^aSingle or tandem ASCT permitted. ^bLen dose: 10 mg once daily; may increase to 15 mg once daily on Day 1 of Cycle 4 (Len) or Cycle 5 (Tec-Len) if 10 mg was tolerated.



EMN30/MajesTEC-4 SRI: Dosing

28-day cycles	Cycle 1	Cycle 2	Cycles 3-6	Cycles 7-26 ^c
Tec QW → Q4W + Len	Tec SUD ^a + Tec 1.5 mg/kg on D8, D15, and D22	Tec 1.5 mg/kg QW + Len	Tec 3.0 mg/kg Q2W + Len	Tec 3.0 mg/kg Q4W ^b + Len
Tec Q4W + Len	Tec SUD ^a + Tec 1.5 mg/kg on D8 and D15	Tec 3.0 mg/kg Q4W ^b + Len		
Tec Q4W	Tec SUD ^a + Tec 1.5 mg/kg on D8 and D15	Tec 3.0 mg/kg Q4W		

- Len was initiated at 10 mg/day from Cycles 2 to 4, followed by 15 mg/day in Cycles 5 to 26, if tolerated
- All cohorts are 2-year fixed-duration maintenance regimens

D, Day; Q2W, every 2 weeks; SUD, step-up dosing.

^aPatients received SUD of 0.06 and 0.3 mg/kg on D1 and D3, respectively. ^bPatients who achieved ≥CR on Tec-Len after Cycle 13 discontinued Tec. ^cPatients on Tec-Len could continue Len after Cycle 26.



EMN30/MajesTEC-4 SRI: Demographic and Disease Characteristics

Characteristic	Tec QW → Q4W + Len (n=32)	Tec Q4W + Len (n=32)	Tec Q4W (n=30)
Median(range) age, y	58.5 (31-73)	58.0 (38-73)	58.5 (34-72)
≥65, n (%)	12 (37.5)	5 (15.6)	9 (30.0)
Male, n (%)	21 (65.6)	21 (65.6)	22 (73.3)
White, race, n (%)	32 (100)	32 (100)	30 (100)
ISS disease stage at diagnosis, n/N (%)			
I	18/32 (56.3)	7/32 (21.9)	9/28 (32.1)
II	7/32 (21.9)	10/32 (31.3)	11/28 (39.3)
III	7/32 (21.9)	15/32 (46.9)	8/28 (28.6)
High cytogenetic risk at diagnosis,^a n/N (%)	7/25 (28.0)	5/29 (17.2)	6/25 (24.0)
Induction regimen for MM, n (%)			
PI ^b + IMiD ^c	28 (87.5)	28 (87.5)	30 (100)
PI ^b + IMiD ^c + anti-CD38 ^d	11 (34.4)	19 (59.4)	20 (66.7)
Prior consolidation, n (%)	6 (18.8)	12 (37.5)	10 (33.3)
Median (range) time from ASCT to maintenance, mo	4.3 (2.0-6.2)	5.1 (1.8-7.4)	4.5 (2.1-6.9)

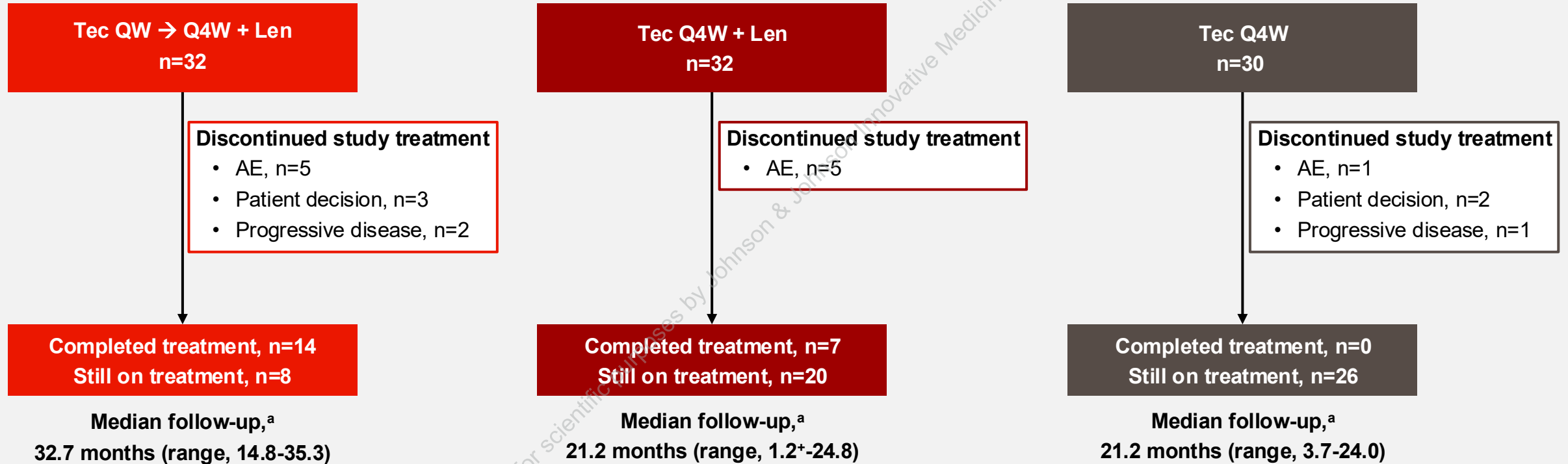
ISS, International Staging System.

^aHigh cytogenetic risk: presence of ≥1 of del(17p), t(4;14), or t(14;16). ^b93/94 (98.9%) received bortezomib and 3/94 (3.2%) received carfilzomib. ^c53/94 (56.4%) received Len, 39/94 (41.5%) received thalidomide, and 1/94 (1.1%) received pomalidomide. ^d50/94 (53.2%) received daratumumab and 1/94 (1.1%) received isatuximab.



EMN30/MajesTEC-4 SRI: Treatment Disposition and Exposure

Safety data cutoff: September 17, 2025



57% of patients remained on treatment and 22% completed fixed-duration treatment at safety cutoff

AE, adverse event.
+=censored observation. ^aAs of the safety data cutoff date.



EMN30/MajesTEC-4 SRI: Hematologic TEAEs

	Cohort 1: Tec QW → Q4W + Len (n=32)		Cohort 2: Tec Q4W + Len (n=32)		Cohort 3: Tec Q4W (n=30)	
Median follow-up, mo	32.7		21.2		21.2	
TEAEs, ^a n (%)	Any grade	Grade 3/4	Any grade	Grade 3/4	Any grade	Grade 3/4
Any TEAE	32 (100)	32 (100)	32 (100)	31 (96.9)	30 (100)	20 (66.7)
Hematologic TEAEs						
Neutropenia	30 (93.8)	30 (93.8)	25 (78.1)	25 (78.1)	22 (73.3)	19 (63.3)
Leukopenia	8 (25.0)	3 (9.4)	0	0	2 (6.7)	1 (3.3)
Lymphopenia	2 (6.3)	1 (3.1)	4 (12.5)	4 (12.5)	6 (20.0)	4 (13.3)
Thrombocytopenia	6 (18.8)	2 (6.3)	1 (3.1)	1 (3.1)	2 (6.7)	0
Anemia	3 (9.4)	0	2 (6.3)	1 (3.1)	3 (10.0)	0
Febrile neutropenia	3 (9.4)	3 (9.4)	3 (9.4)	3 (9.4)	0	0
Eosinophilia	1 (3.1)	1 (3.1)	1 (3.1)	1 (3.1)	0	0

- Median relative dose intensity^b:
 - Tec: 96-99%^c; Len: 55-56%
- Discontinuation due to TEAEs^d
 - Cohort 1: 4 (12.5%)
 - Cohort 2: 4 (12.5%)
 - Cohort 3: 1 (3.3%)
- Two Grade 5 TEAEs
 - COVID-19 (Cohort 2)
 - Radiculopathy (Cohort 2)
- Two non-TEAE deaths
 - Complications after allo-SCT (Cohort 1)^e
 - Progressive disease (Cohort 3)

High median RDI maintained with Tec and low rates of discontinuation due to TEAEs

allo-SCT, allogenic stem cell transplant; MDS, myelodysplastic syndrome; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; RDI, relative dose intensity; TEAE, treatment-emergent adverse event. ^aAEs (graded per NCI-CTCAE Version 5.0); any grade in >25% of patients or grade 3/4 in >1 patient. ^bRatio of total dose actually received/total planned dose per protocol. Planned doses not received due to study drug discontinuation are excluded. ^cIncludes SUD as well as repeat SUD if applicable. ^dDiscontinuation of all study treatment. ^ePatient developed MDS and had a fatal event due to severe immunosuppression after allo-SCT unrelated to study treatment.



EMN30/MajesTEC-4 SRI: Nonhematologic TEAEs

	Tec QW → Q4W + Len (n=32)		Tec Q4W + Len (n=32)		Tec Q4W (n=30)	
Median follow-up, mo	32.7		21.2		21.2	
TEAEs, ^a n (%)	Any grade	Grade 3/4	Any grade	Grade 3/4	Any grade	Grade 3/4
Nonhematologic TEAEs^b						
URTI	22 (68.8)	1 (3.1)	13 (40.6)	0	12 (40.0)	0
Diarrhea	17 (53.1)	3 (9.4)	12 (37.5)	1 (3.1)	8 (26.7)	0
CRS	16 (50.0)	0	13 (40.6)	0	13 (43.3)	0
Cough	14 (43.8)	0	8 (25.0)	0	10 (33.3)	0
COVID-19	13 (40.6)	1 (3.1)	7 (21.9)	0	9 (30.0)	1 (3.3)
Injection-site erythema	7 (21.9)	0	12 (37.5)	0	9 (30.0)	0
Fatigue	10 (31.3)	1 (3.1)	9 (28.1)	1 (3.1)	6 (20.0)	0
PSN	5 (15.6)	0	9 (28.1)	0	2 (6.7)	0
Pneumonia	8 (25.0)	4 (12.5)	3 (9.4)	0	2 (6.7)	1 (3.3)

- All CRS was grade 1/2 (38.3%/6.4%)
 - Most occurred after SUD 1/SUD 2 (37.2%/8.5%)
 - All resolved and no discontinuations
 - 11.7% received tocilizumab for CRS treatment
- No ICANS

CRS was mostly grade 1 and occurred during SUD, with no Tec discontinuations

CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; PSN, peripheral sensory neuropathy; URTI, upper respiratory tract infection.

^aAEs (graded per NCI-CTCAE Version 5.0); any grade in >25% of patients or grade 3/4 in >10% of patients. ^bHypogammaglobulinemia based on TEAE reporting also met the ≥25% threshold and is reported separately.



EMN30/MajesTEC-4 SRI: Infections and Hypogammaglobulinemia

	Cohort 1: Tec QW → Q4W + Len (n=32)		Cohort 2: Tec Q4W + Len (n=32)		Cohort 3: Tec Q4W (n=30)	
Median follow-up, mo	32.7		21.2		21.2	
TEAEs, ^a n (%)	Any grade	Grade 3/4	Any grade	Grade 3/4	Any grade	Grade 3/4
Any infection	31 (96.9)	12 (37.5)	28 (87.5)	11 (34.4)	27 (90.0)	8 (26.7)
Most common infections^b						
URTI	22 (68.8)	1 (3.1)	13 (40.6)	0	12 (40.0)	0
COVID-19	13 (40.6)	1 (3.1)	7 (21.9)	0	9 (30.0)	1 (3.3)
Nasopharyngitis	6 (18.8)	0	4 (12.5)	0	3 (10.0)	0
Bronchitis	5 (15.6)	0	1 (3.1)	0	4 (13.3)	1 (3.3)
Influenza	7 (21.9)	0	2 (6.3)	0	3 (10.0)	0
Pneumonia	8 (25.0)	4 (12.5)	3 (9.4)	0	2 (6.7)	1 (3.3)
Rhinovirus infection	3 (9.4)	0	4 (12.5)	0	0	0

- Hypogammaglobulinemia^c reported in:
 - Cohort 1: 31 (96.9%)
 - Cohort 2: 28 (87.5%)
 - Cohort 3: 28 (93.3%)
- IgRT and antimicrobial prophylaxis was strongly recommended^d
- One grade 5 COVID-19 TEAE occurred in Cohort 2

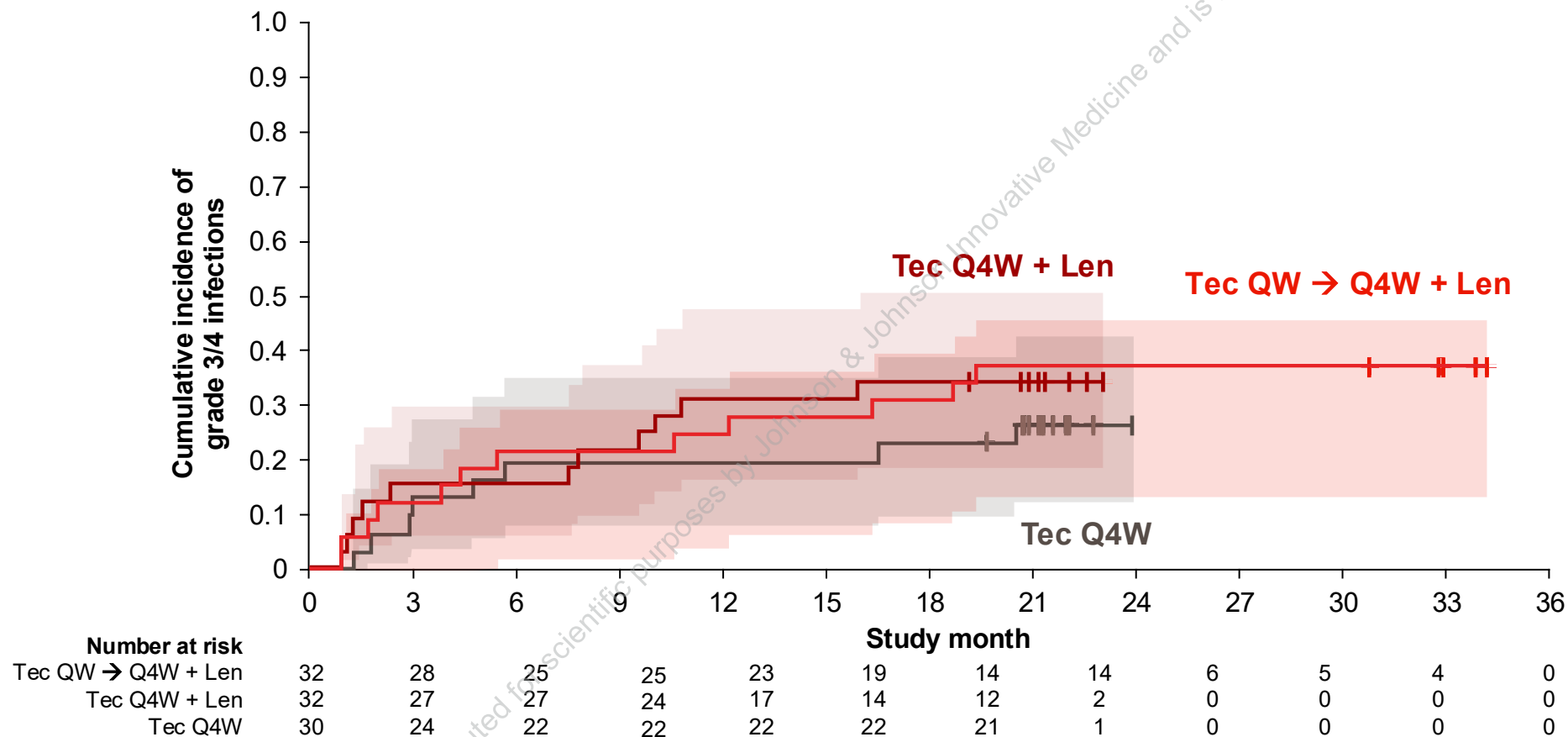
Grade 3/4 infections lowest with Tec Q4W, consistent with disease control and monthly dosing

Ig, immunoglobulin; IgG, immunoglobulin G; IgRT, immunoglobulin replacement therapy.

^aAEs (graded per NCI-CTCAE Version 5.0). ^bAny grade in >10% of patients. ^cPatients with ≥1 TEAE of hypogammaglobulinemia or postbaseline IgG value <400 mg/dL. ^dProphylactic IgRT advised to maintain serum IgG levels of ≥400 mg/dL; all patients with ≥1 TEAE of hypogammaglobulinemia or postbaseline IgG value <400 mg/dL received ≥1 dose of IgRT. Prophylaxis for *Pneumocystis jirovecii* pneumonia and herpes zoster reactivation recommended, as well as routine antibiotic and antiviral prophylaxis.



EMN30/MajesTEC-4 SRI: Cumulative Incidence of Grade 3/4 Infections

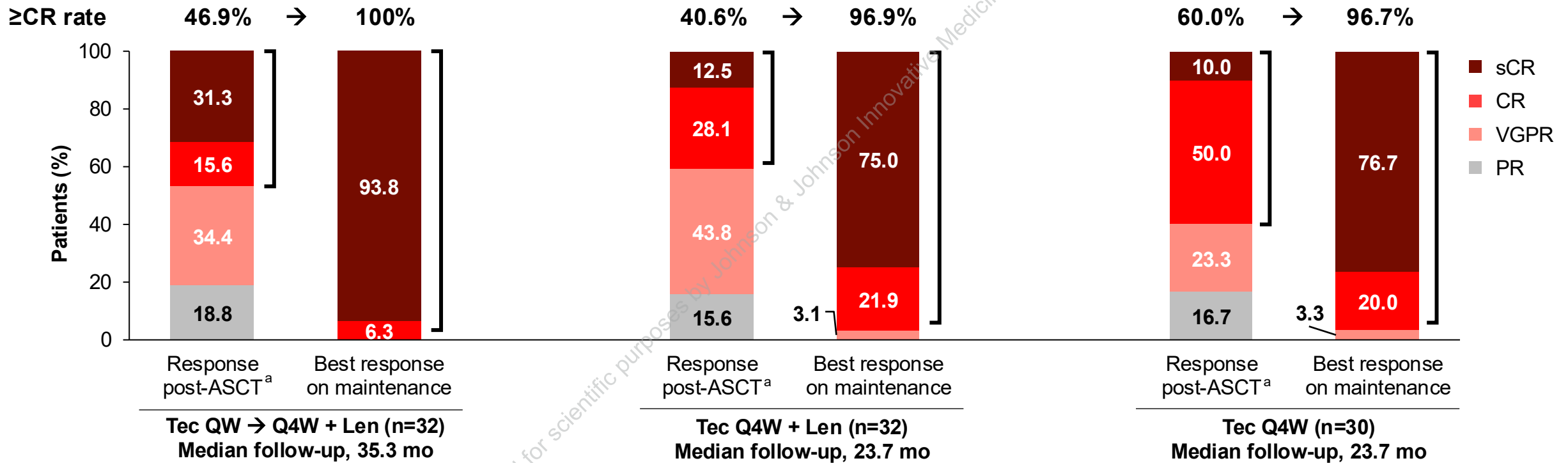


Cumulative incidence of grade 3/4 infections plateaued with Tec Q4W from ~6 months



EMN30/MajesTEC-4 SRI: Response Rates Post-ASCT and During Maintenance

Efficacy data cutoff: December 8, 2025

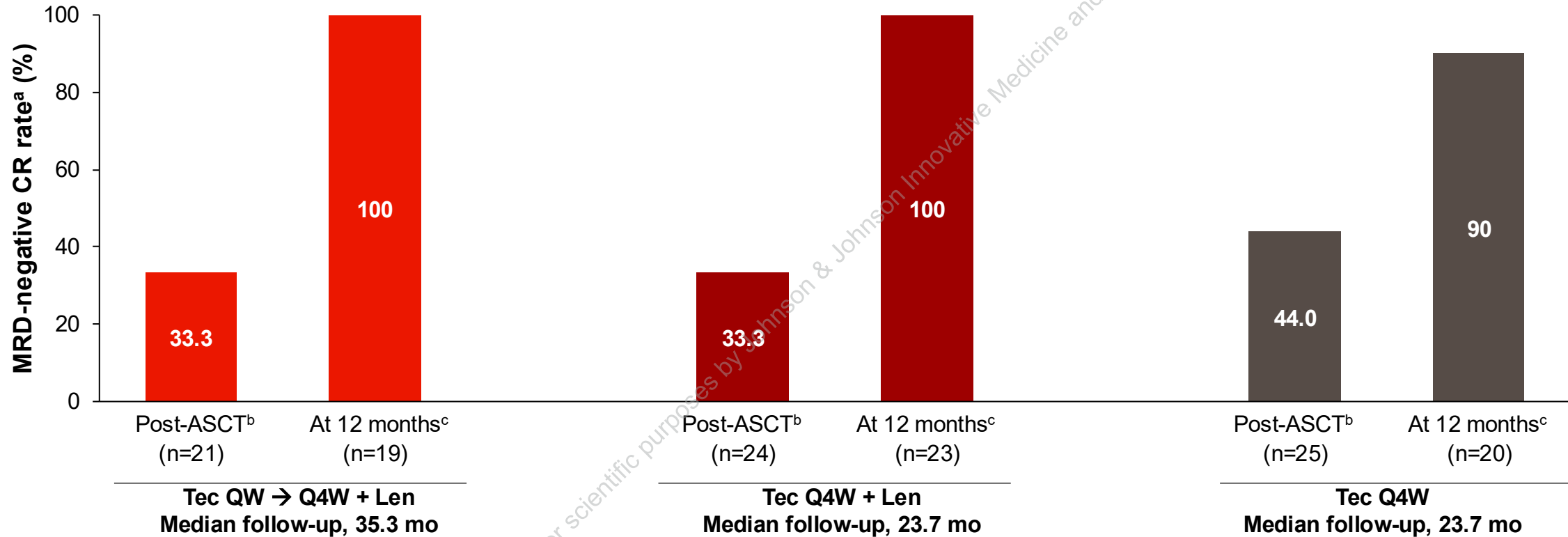


≥CR was reached in nearly 100% of patients during maintenance across cohorts

sCR, stringent complete response; VGPR, very good partial response.
Response based on investigator assessment. ^aPost-ASCT ± consolidation.



EMN30/MajesTEC-4 SRI: MRD-Negative (10^{-5}) CR Rate by NGF in Evaluable Patients



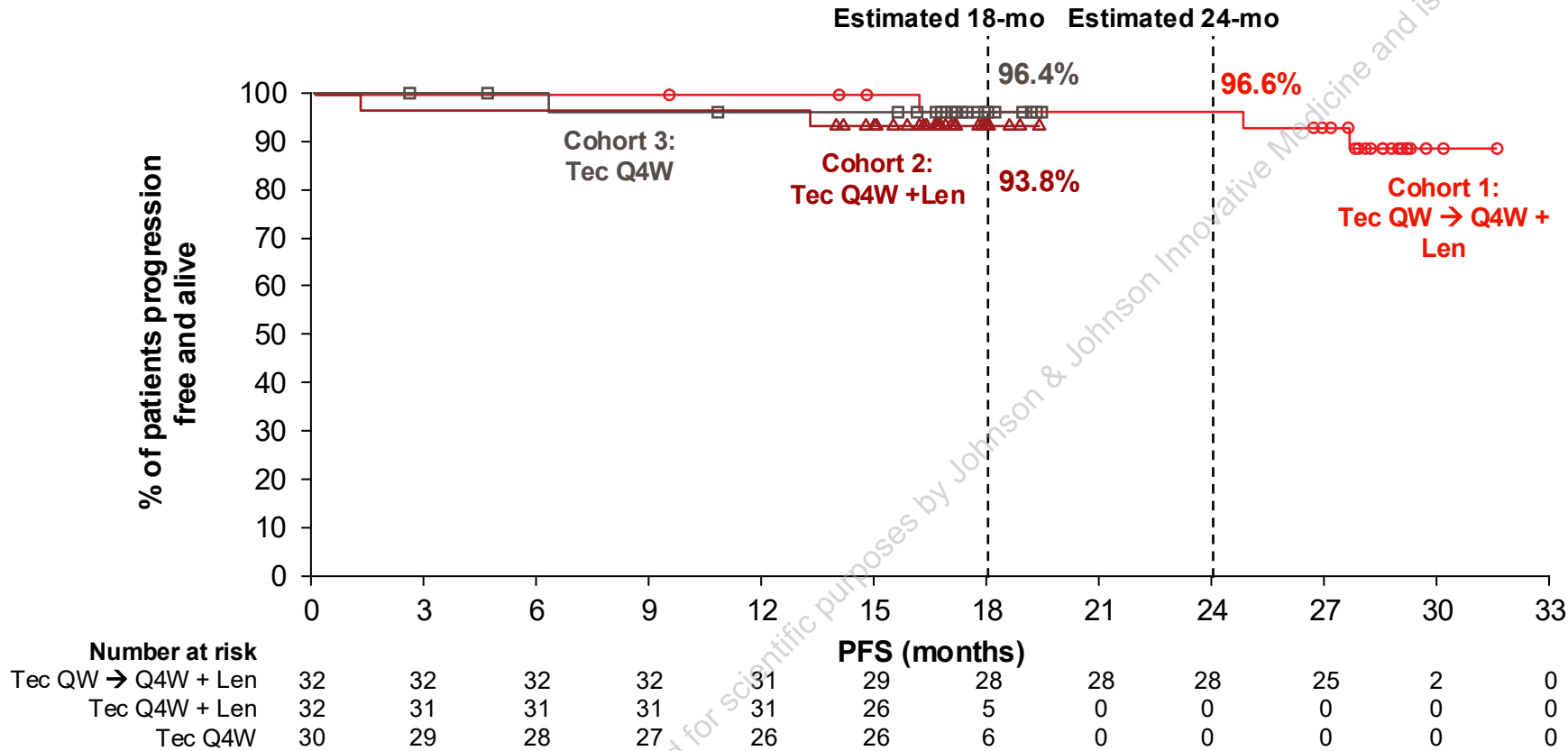
Almost all evaluable patients achieved MRD-negative CR during maintenance

PD, progressive disease.

^aMRD-negative CR rate: the proportion of evaluable patients who achieved MRD negativity (10^{-5}) by NGF and \geq CR by investigator; MRD negativity must occur within 3 mo before or any time after \geq CR, and prior to PD or start of subsequent therapy. For post-ASCT, evaluable patients: ≥ 1 MRD sample with sufficient cells for evaluation at the testing threshold that resulted in positive or negative on or prior to maintenance start. For 12 mo post-maintenance, evaluable patients: (a) ≥ 1 MRD sample with sufficient cells for evaluation that resulted in positive or negative between 9 and 15 mo and prior to PD or start of subsequent therapy; or (b) PD prior to 9 mo, or (c) MRD sample that resulted in negative before 9 mo and after 15 mo, with no MRD positive in between prior to PD or start of subsequent therapy. ^bPost-ASCT \pm consolidation. ^c12 mo (+/- 3 mo) post-maintenance.



EMN30/MajesTEC-4 SRI: Progression-Free Survival



- Median PFS was not reached in any cohort
- Only 3 patients progressed
 - 2 in Cohort 1
 - 1 in Cohort 3

Estimated 18- and 24-month PFS rates were 94%-97%, with only 3 progression events

Clinical cutoff date: May 7, 2025.



EMN30/MajesTEC-4 SRI: Tec ± Len as Maintenance Therapy Post-ASCT in NDMM

- Tec and Tec-Len were safely administered as 2-year fixed-duration post-ASCT maintenance, with convenient Tec Q4W dosing after cycle 1 (median follow-up ~2–3 years)
- CRS and infections were manageable via established protocols, supporting use across practice settings
- Tec-based maintenance delivered remarkable depth of response post-ASCT, which deepened over time:
 - 97%–100% of patients achieved \geq CR post-ASCT
 - 90%–100% of evaluable patients achieved MRD-negative CR at 12 months
- Estimated 18- and 24-mo PFS rates were 94%–97%, with only 3 progression events
- The randomized portion is open and evaluating Tec-Len, Tec, and Len as maintenance with monthly Tec dosing

Tec ± Len as post-ASCT maintenance in NDMM is a promising new maintenance approach



EMN30/MajesTEC-4: Participating Countries



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- Staff members at the study sites
- Data and safety monitoring committee
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- This study was sponsored by EMN in collaboration with Johnson & Johnson



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